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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,027	03/02/2004	John A. Giordano	48508-00014	9737

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EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,027	GIORDANO ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *187-201 and 217-231* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *187-201 and 217-231* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20050406,20050406*.20040811
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice of Non-Compliant Amendment*

DETAILED ACTION

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See paragraphs 0041-0043, 0046,0047 of the Specification. Since the Amendment to the Specification has not been entered (See Notice of Non-Compliant Amendment), the objection herein is maintained.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 187, 190, 193, 195-201 are rejected under 35 U.S.C. 102(e) as being anticipated by Nidamarty et al. (US 2003/0206969).

Nidamarty et al. expressly discloses a composition containing Vitamin A, Vitamin D , Vitamin C, Vitamin E, folic acid, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, niacinamide, calcium (calcium carbonate), iron (ferrous fumarate), magnesium (magnesium

oxide), zinc (zinc oxide), and copper (cupric oxide) as a dietary supplement (Nidamarty et al., Claims 36,38). Vitamin C is ascorbic acid, Vitamin B2 is riboflavin, and Vitamin B12 is cyanocobalamin (See Drug Facts and Comparisons (1999), pgs. 4-33,36-39,48,49 and Remington's (17th Ed. 1985), pgs. 1002-1009, 1011-1025,1030-1034 cited herein solely as extrinsic evidence).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

The Declaration filed on 2/11/2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the cited reference.

The cited reference is a U.S. patent application publication of a pending application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

Claims 187-201, 217-231 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nidamarty et al. (US 2003/0206969).

Nidamarty et al. discloses a composition containing Vitamin A (about 0.002 mg to about 15 mg), Vitamin D (about 0.001 mg to about 0.6 mg), Vitamin C (about 10-1000 mg), Vitamin E (about 1 mg to about 125 mg), Vitamin B1 (about 0.5-50 mg), Vitamin B2 (about 0.5-50 mg), Vitamin B6 (about 0.1-200 mg), Vitamin B12 (about 2 –250 mcg), niacinamide (about 1-100 mg), calcium (calcium carbonate) (about 20-1000 mg, about 80-

110 mg, 100 mg), iron (ferrous fumarate) (about 10-200 mg), magnesium oxide (about 0.1-400 mg), zinc oxide (about 5-100 mg) and cupric oxide (about 0.1-10 mg) as a dietary supplement (Nidamarty et al., Claims 35,36,38).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the claimed amounts of vitamins and minerals within the scope of about 2430 IU to about 2970 IU Vitamin A, about 63 mg to about 77 mg Vitamin C, about 27 IU to about 33 IU Vitamin E, about 1.44 mg to about 1.76 mg Vitamin B1, about 1 .62 mg to about 1 .98 mg Vitamin B2, about 2.25 mg to about 2.75 mg Vitamin B6, about 58.5 mg to about 71.5 mg iron wherein said composition is free of any other added minerals and any other added vitamins other than Vitamin A, Vitamin D, Vitamin C, Vitamin E, folic acid, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, niacin, calcium, iron, magnesium, zinc, and copper. Further, the prior art does not expressly disclose in the claims the use of beta carotene, cholecalciferol, dl-alpha-tocopheryl acetate, thiamine mononitrate or pyridoxine hydrochloride. However, the prior art amply suggests the same as amounts near and/or encompassing the claimed amounts are disclosed by the prior art and Vitamin A, Vitamin D, Vitamin C, Vitamin E folic acid, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, niacinamide, calcium (calcium carbonate), iron (ferrous fumarate), magnesium (magnesium oxide), zinc (zinc oxide), and copper (cupric oxide) are disclosed.

As such, it would have been well within the skill of one of ordinary skill in the art to modify the prior art depending on the amount of each vitamin or mineral desired in the composition with the expectation that said amount would be suitable for use in a dietary supplement (See In re Peterson, 65 USPQ2d 1379, 1382, 1383 (CAFC 2003) (a *prima facie* case of obviousness exists where the ranges overlap, are close enough such that one of ordinary skill

in the art would expect them to have the same properties or where a somewhat broader range encompasses the claimed narrower range). Further, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use any pharmaceutically acceptable form or equivalent form of Vitamin A, Vitamin D, Vitamin E, Vitamin B1, Vitamin B6, with the expectation that the same would be suitable as a nutritional supplement.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons as above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 187-201, 217-231 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of US Pat. 6,814,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both set forth compositions containing the same vitamins and minerals with claims

1-4 of said US Patent anticipating claims 187, 217 by claiming amounts which are encompassed by the scope of the claims 187,217.

The difference between the claims of the '445 patent and the claimed invention is that said claims do not expressly disclose the specific forms of Vitamin A, Vitamin D, Vitamin E, Vitamin B1, Vitamin B6, niacin, calcium, iron, magnesium, zinc, and copper set forth in the dependent claims 188, 189, 191,192, 194, 196, 197-201, 218, 219, 221, 222,224, 226-231. However, the prior art amply suggests the same as Vitamin A, Vitamin D, Vitamin E, Vitamin B1, Vitamin B6, niacin, calcium, iron, magnesium, zinc, and copper are disclosed in the '445 patent. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use any pharmaceutically acceptable form or equivalent form of vitamins and minerals set forth in claims 1-4 of said US patent with the expectation that the same would be suitable as a nutritional supplement.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Examiner is unclear what Applicant means by asking to defer the rejection until there is allowable subject matter. If the claims are rejected under double patenting, Examiner cannot issue an allowance. Applicant must traverse and/or file an amendment which avoids the double patenting rejection or file a terminal disclaimer. If Applicant defers in addressing the double patenting issue as indicated then the rejection must be maintained.

Therefore, the claimed invention, as a whole, would have been obvious modification of the claims of the '445 patent to one of ordinary skill in the art at the time the invention was made, because every element of the invention has taught by the teachings of said claims.

Claims 187-201, 217-231 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of US Pat. 6,814,983 in view of Manning et al. (US Pat. 6,569,445) or Nidamarty et al. (US 2003/0206969).

Claims 1-4 disclose a composition comprising Vitamin A, Vitamin D, Vitamin C, Vitamin E, folic acid, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, niacin, calcium, iron, magnesium, zinc, and copper, wherein said composition is administrable to a patient, and wherein said composition is free of any other added minerals and any other added vitamins.

Manning et al. discloses that the use of vitamins and minerals such as beta-carotene, cholecalciferol, ascorbic acid, dl-alpha-tocopheryl acetate, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamine, niacinamide, calcium carbonate, ferrous fumarate, magnesium oxide, zinc oxide, cupric oxide as a dietary supplement (Manning et al., Column 7, lines 60-68, Column 8, Column 9, lines 1-10

Nidamarty et al. discloses a composition containing Vitamin A (about 0.002 mg to about 15 mg), Vitamin D (about 0.001 mg to about 0.6 mg), Vitamin C (about 10-1000 mg), Vitamin E (about 1 mg to about 125 mg), Vitamin B1 (about 0.5-50 mg), Vitamin B2 (about 0.5-50 mg), Vitamin B6 (about 0.1-200 mg), Vitamin B12 (about 2 –250 mcg), niacinamide (about 1-100 mg), calcium (calcium carbonate) (about 20-1000 mg, about 80-110 mg, 100 mg), iron (ferrous fumarate) (about 10-200 mg), magnesium oxide (about 0.1-400 mg), zinc oxide (about 5-100 mg) and cupric oxide (about 0.1-10 mg) as a dietary supplement (Nidamarty et al., Claims 35,36,38).

The difference between the claims of the '445 patent and the claimed invention is that said claims do not expressly disclose the specific forms of Vitamin A, Vitamin D, Vitamin E, Vitamin B1, Vitamin B6, niacin, calcium, iron, magnesium, zinc, and copper set forth in the

dependent claims 188, 189, 191,192, 194, 196, 197-201, 218, 219, 221, 222,224, 226-231. However, the prior art amply suggests the same as Vitamin A, Vitamin D, Vitamin E, Vitamin B1, Vitamin B6, niacin, calcium, iron, magnesium, zinc, and copper are disclosed in the '445 patent. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use any pharmaceutically acceptable form or equivalent form of vitamins and minerals set forth in claims 1-4 of said US patent with the expectation that the same would be suitable as a nutritional supplement.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons as above.

Therefore, the claimed invention, as a whole, would have been obvious modification of the claims of the '445 patent to one of ordinary skill in the art at the time the invention was made, because every element of the invention has taught by the teachings of said claims.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
April 30, 2005

SABIHA QAZI, PH.D
PRIMARY EXAMINER

Notice of Non-Compliant Amendment (37 CFR 1.121)	Application No. 10/790,027	Applicant(s) GIORDANO ET AL.	
	Examiner Frank I. Choi	Art Unit 1616	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

The amendment document filed on *11 February 2005* is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

☒ 1. Amendments to the specification:
- ☒ A. Amended paragraph(s) do not include markings.
- ☐ B. New paragraph(s) should not be underlined.
- ☒ C. Other *Although Applicant has also submitted a marked-up version of the amendment, the title of the amendment to the Specification is required to be "Amendments to the Specification", as such, the title "Marked-up Amendments to the Specification" is improper. Further, said marked-up version contains no instructions as to location and replacement of paragraphs. See MPEP Section 714 [R-2](II).*

☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
- ☐ B. Other _____.

☐ 3. Amendments to the drawings:
- ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
- ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
- ☐ C. Other _____.

☐ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
- ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
- ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
- ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
- ☐ E. Other: _____.

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714 and the USPTO website at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf .

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted within the time period set forth in the final Office action.
2. Applicant is given ~~one month, or thirty (30) days, whichever is longer,~~ three months from the mail date of this notice to supply the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action.

4/20/05 SC

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:
Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or
Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.